

Having thus described the invention, what is claimed and desired to be secured by Letters Patent is:

- 5 1. A method for analysing data from a polymerase chain reaction, the reaction
amplifying an amount of reaction product during a plurality of reaction
cycles, including:
 - measuring a signal representative of the amount of reaction product for
each of the cycles, and
 - calculating a reaction by estimating a slope of the dependence of a
10 logarithm of the signal on cycle number for a set of cycles over which
the dependence is substantially linear.
2. The method of claim 1, wherein the signal is a fluorescent signal.
- 15 3. The method of claim 1, wherein the slope is estimated from a linear
regression.
4. The method of claim 1, wherein the slope is estimated by averaging the
difference of the signal between adjacent cycles over the set of cycles.
- 20 5. The method of claim 1, further including calculating a noise level and a
saturation level for the signal and wherein,
 - if the set contains an odd number of cycles, the set of cycles is centered
on the cycle for which the signal is closest to the average of the noise
25 and saturation levels, and,
 - if the set contains an even number of cycles, the set of cycles is centered
on the two cycles for which the signal is closest to the average of the
noise and saturation levels.

6. The method of claim 5, wherein the slope is estimated from a linear regression and the number of points in the set is selected such that the coefficient of determination of the linear regression is maximised.
- 5 7. A method for calculating the efficiency of a polymerase chain reaction which runs for a plurality of cycles, from a dependence of a signal representative of an amount of reaction product on cycle number, wherein the efficiency is calculated by estimating a slope of the dependence of a logarithm of the signal on the cycle number for a set of cycles over which
10 the dependence is substantially linear.
8. The method of claim 7, wherein the signal is a fluorescent signal.
9. The method of claim 7, wherein the slope is estimated from a linear
15 regression.
10. The method of claim 7, wherein the slope is estimated by averaging the difference of the signal between adjacent cycles over the set of cycles.
- 20 11. The method of claim 7, including calculating a noise level and a saturation level for the signal and wherein,
if the set contains an odd number of cycles, the set of cycles is centered on the cycle for which the signal is closest to the average of the noise and saturation levels, and,
25 if the set contains an even number of cycles, the set of cycles is centered on the two cycles for which the signal is closest to the average of the noise and saturation levels.

12. The method of claim 11, wherein the slope is estimated from a linear regression and the number of points in the set is selected such that the coefficient of determination of the linear regression is maximised
- 5 13. A method for analysing data from a polymerase chain reaction including measuring a signal representative of an amount of reaction product for each of a plurality of cycles and analysing a dependence of the logarithm of the signal on the cycle numbers for a set of cycles over which the dependence is linear.
- 10 14. The method of claim 13, including calculating a noise level and a saturation level for the signal; and wherein the set of cycles is centered on the cycle for which the signal is closest to the average of the noise and saturation levels.
- 15 15. A system for analysing data from a polymerase chain reaction, the reaction amplifying an amount of reaction product during a plurality of reaction cycles, the system including:
- 20 a memory for storing a signal representative of the amount of reaction product for each of the cycles,
a processing unit for calculating a logarithm of the signal,
a memory for storing the logarithm, and
a reaction efficiency calculator, for calculating reaction efficiency from a dependence of the signal on the cycle number;
- 25 the system further comprising a selector adapted to select a set of cycles over which the dependence of the logarithm on the cycle number is substantially linear, and

wherein the efficiency calculator includes an estimator for estimating a slope of the dependence of the logarithm of the signal on the cycle number for the selected set of cycles.

5 16. The system of claim 15, wherein the signal is a fluorescent signal.

17. The system of claim 15, wherein the estimator is arranged to linearly regress the signal against cycle number for the said set of cycles.

10 18. The system of claim 15, wherein the estimator is arranged to average the difference of the signal between adjacent cycles over the said set of cycles.

15 19. The system of claim 15, further including a processing unit for calculating a noise level and a saturation level for the signal and wherein the selector is arranged to select:

if the set contains an odd number of cycles, the set of cycles centered on the cycle for which the signal is closest to the average of the noise and saturation levels, and,

20 if the set contains an even number of cycles, the set of cycles centered on the two cycles for which the signal is closest to the average of the noise and saturation levels.

20. The system of claim 19, wherein the estimator is arranged to linearly regress the signal against cycle number for the said set of cycles.

25 21. The system of claim 20, wherein the selector is arranged to select the number of points in the set such that the coefficient of determination of the linear regression is maximised.

22. A method for analysing data from polymerase chain reactions on a plurality of samples, the reactions amplifying an amount of reaction product during a plurality of reaction cycles, including
- 5 measuring a signal representative of the amount of reaction product for each of the cycles and each of the samples,
- calculating an average signal by averaging the signals obtained for each of the samples; and
- calculating a reaction efficiency by estimating a slope of the dependence of a logarithm of the averaged signal on the cycle number for a set of
- 10 cycles over which the dependence is substantially linear.
23. A method for analysing data from polymerase chain reactions applied to a plurality of samples, the reactions amplifying an amount of reaction product during a plurality of reaction cycles, including:
- 15 measuring a signal representative of the amount of reaction product for each of the cycles and each of the samples, and
- calculating a reaction efficiency by estimating a slope of the dependence of the logarithm of the averaged signal on the cycle number for a set of cycles over which the dependence is substantially linear,
- 20 and calculating an average efficiency for the plurality of samples by averaging the efficiencies calculated for each of the samples.
24. The method any one of the preceding claims in which the calculation is carried out in real-time as the polymerase chain reaction proceeds.
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25. A medical diagnostic method comprising obtaining a biological sample, determining the efficiency of a polymerase chain reaction applied to the sample, the reaction amplifying an amount of reaction product during a plurality of reaction cycles, by measuring a signal representative of the

amount of reaction product for each of the cycles, and estimating a slope of the dependence of a logarithm of the signal on cycle number for a set of cycles over which the dependence is substantially linear.

- 5 26. A method of calculating the initial load of a reaction product within a biological sample, comprising:
- applying a polymerase chain reaction to the sample over a plurality of cycles, the reaction amplifying the reaction product for each of the cycles,
- 10 measuring a signal representative of the amount of reaction product for each of the cycles, and
- calculating the initial load by estimating a zero intercept of a line representative of a logarithm of the signal against cycle number for a set of cycles over which the dependence is substantially linear.

- 15 27. A medical diagnostic method comprising obtaining a biological sample, and:
- applying a polymerase chain reaction to the sample over a plurality of cycles, the reaction amplifying the reaction product for each of the cycles,
- 20 measuring a signal representative of the amount of reaction product for each of the cycles, and
- calculating the initial load by estimating a zero intercept of a line representative of a logarithm of the signal against cycle number for a set of cycles over which the dependence is substantially linear.
- 25 28. The method of claim 27 in which the reaction product is virus or bacteria-based.

29. The method of claim 27 in which the reaction product is gene-based.
30. The method of claim 27 in which the reaction product comprises a vector-based product, the method being used to determine the amount of vector
5 that has been taken up after gene therapy.
31. A method of genotyping comprising determining the gene level within a biological sample by:
- 10 creating a gene-based reaction product with the sample, applying a polymerase chain reaction to the sample over a plurality of cycles, the reaction amplifying the reaction product for each of the cycles, measuring a signal representative of the amount of reaction product for each of the cycles, and
- 15 calculating the initial load by estimating a zero intercept of a line representative of a logarithm of the signal against cycle number for a set of cycles over which the dependence is substantially linear.